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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,881	06/20/2003	John S. Brandstetter	P-10169.00	6677

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MEDTRONIC, INC.
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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
- 3 MONTHS -	04/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.		Applicant(s)	
	10/600,881		BRANDSTETTER ET AL.	
	Examiner		Art Unit	
	George R. Evanisko		3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/24/06 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The subject matter which is not enabled is the method step or element for "satisfaction of at least one pre-detection criteria associated with potential detection of a tachyarrhythmia episode" in combination with the other elements or steps in the claims. The original specification and claims state that there is pre-detection criteria for potential detection of a tachyarrhythmia episode but never discuss what this pre-detection criteria is. Is the criteria a high heart rate, a medium high heart rate, PVCs, a wide QRS, narrow QRS, etc.? It is unclear what constitutes the pre-detection criteria and if this is the same as an actual detection of a tachyarrhythmia episode.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 7, 13, and 19, “of the type that has” is vague and does not specifically point out the limits and scope of something that is “of the type” (it is suggested to delete the phrase and insert “having”); “a sensing threshold” is inferentially included and it is unclear if the threshold is being positively recited or functionally recited (it is suggested to first recite the sense amplifier having the threshold); “for use detection” should be “for use in detection”; “with subsequent delivery of therapy” is vague since the method/system has not set forth any element or step to deliver therapy--it is unclear whether therapy is being delivered and whether there is structure or steps for delivering therapy; and “in response to the tachycardia episode” is vague since there has only be a “potential detection” of tachycardia and it is unclear if this is the same thing or not (and if it’s the same as a potential detection, then why is therapy being delivered).

In addition, “at least one pre-detection criteria associated with potential detection of a tachyarrhythmia episode” is vague since it is unclear if this applies only to the possibility of a tachyarrhythmia or if this applies to the actual detection of a tachyarrhythmia episode.

In claims 2, 6, 8, and 12, “is adjusted” is in the passive voice and is not positively reciting a method step. It is suggested to use active voice, such as “further comprising adjusting the sensing threshold...”.

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In claims 5, 11, 17, and 23, “to at least one pre-detection criteria” is vague since it is unclear if this is the same as the pre-detection criteria used in the independent claims or different criteria (“to said at least...”).

In claims 13 and 19, “In an implantable device...., a system comprising” is vague. It is unclear if the implantable device is part of the system, whether it is a combination of the system and IMD, or whether the IMD is being positively recited. In addition for claim 13, the “external device” is inferentially included.

In claims 14, 18, 20, and 24, the claims are vague since they do not set forth what element is performing the adjustment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nau et al (5732708) in view of Paul et al (5944744). Nau describes the use of his system in an implantable cardioverter defibrillator (e.g. col. 1, line 8) using trigger events to trigger the storage of EGM data such as QRS complexes and depolarizations (e.g. col. 3, lines 10-15), along with the initial diagnosis of fibrillation or tachyarrhythmia, therapy delivered or aborted, etc (e.g. col. 13, lines 24-44, col. 8, lines 30-50, col. 9, lines 60-67) and that there are detections of “potential episodes” (the claimed “pre-detection criteria”) of arrhythmias that will be crosslinked/associated with the EGM data (e.g. col. 10, lines 1-4). Nau also discloses that this data is telemetered out to an external programmer where the physician uses the data to tweak the ICD settings or parameters (e.g. col. 3, lines 32-40, col. 8, lines 16-20) and therefore provides motivation to have the external programmer/physician modify device settings. In addition, since Nau records the EGM and telemeters it out, he therefore inherently measures the peak amplitude since the recorded EGM represents a measured cardiac signal.

But Nau does not specifically disclose the ICD has a sense amplifier that detects cardiac signals with intrinsic heart depolarizations that exceed a threshold, using those senses for processing for detection/ pre-detection of tachyarrhythmia, transmitting the peak amplitudes to an external device, and having the external device adjusting the sensing threshold to ensure sensing. Paul discloses an ICD (e.g. col. 1) that has a sense amplifier that detects cardiac signals with intrinsic heart depolarizations that exceed a threshold, transmitting the peak amplitudes to an external device, and having the external device adjust the sensing thresholds to ensure sensing, all to provide optimal sensitivity for detecting and processing the patient’s cardiac signal and allow the physician to place limits on the sensitivity changes. Paul also states that it is

known that during onset and progression of tachycardia and fibrillation that the amplitude of the electrical events varies widely and means are needed to cope with the amplitude variations, such as thresholds (e.g. col. 3).

It would have been obvious at the time the invention was made to incorporate in the ICD method and system as taught by Nau, the use of a sense amplifier that detects cardiac signals with intrinsic heart depolarizations that exceed a threshold, transmitting the peak amplitudes to an external device, and having the external device adjust the sensing thresholds to ensure sensing as taught by Paul, since such a modification would provide an ICD method and system with a sense amplifier that detects cardiac signals with intrinsic heart depolarizations that exceed a threshold, transmitting the peak amplitudes to an external device, and having the external device adjust the sensing thresholds to ensure sensing, all to provide optimal sensitivity for detecting and processing the patient's cardiac signal and allow the physician to place limits on the sensitivity changes.

In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ICD system and method as taught by Nau or Nau in view of Paul, with the use of the sensed intrinsic events for processing for detection/ pre-detection of tachyarrhythmia since it was known in the art that ICD methods and systems use the sensed intrinsic events, such as R and P waves, for processing for detection/ pre-detection of tachyarrhythmia to allow the ICD to conventionally and easily determine when the heart rate has exceeded criteria for indicating fibrillation or tachycardia and delivering appropriate therapy to treat the arrhythmia.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wilson et al and Conley are other examples of many showing the use of pre-detection criteria (PVCs, high rate, etc) and the storage of peak amplitude data and therapy data. Hsu teaches the use of peak amplitudes, sense amplifiers, and association of therapy delivered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

George R Evanisko
Primary Examiner
Art Unit 3762

4/13/7

GRE
April 12, 2007